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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/462,682      | 04/28/00    | FITZGERALD           | D 015280-31010      |

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HM22/0608

EXAMINER

PORTNER, V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1645     | 5            |

DATE MAILED: 06/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

|                               |                            |
|-------------------------------|----------------------------|
| Application No.<br>09/462,682 | Applicant(s)<br>Fitzgerald |
| Examiner<br>Portner           | Art Unit<br>1645           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 28, 2000.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-43 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-43 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

Claims 1-43 are pending.

In view of Pastan et al (US Pat. 5,324,984) that discloses a chimeric protein that is immunogenic and comprises a non-toxic Pseudomonas exotoxin A-like protein (lacks ADP-ribosylating activity and amino acid 553 deleted), a cell recognition domain, an ER retention domain and a non-native epitope (antigen that comprises a non-native epitope), the first appearing claimed invention (claim 1) does not define a special technical feature over the prior art. (see Figure 2, col. 8, line 3 (defines the components of the chimera as immunogenic) and col. 9, lines 5-9).

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, 27-32, 24-26, 33-38 drawn to chimeric immunogens that comprise non-toxic Pseudomonas exotoxin A and a non-native epitope and methods of stimulating an immune response.

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Group II, claim(s) 19-23 and 39, drawn to a nucleic acid sequence.

Group III, claim(s) 40-43, drawn to a second method of immunizing a subject with a nucleic acid sequence containing composition.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (choose one from the first column and one from the second column)

| <b>Group I: cell recognition domain</b>    | <b>non-native epitope</b>                  |
|--|--|
| 1. Binds alpha2-macroglobulin              | cysteine-cysteine loop                     |
| 2. Binds epidermal growth factor receptor  | SEQ ID NO 3                                |
| 3. Binds IL-2 receptor                     | SEQ ID NO 4                                |
| 4. Binds HIV-infected cells                | V3 loop of gp120 of HIV-1                  |
| 5. Binds a chemokine receptor              | V3 loop of gp120 of HIV-1(>=8aa)           |
| 6. Binds a leukocyte cell surface receptor | V3 domain of HIV-1                         |
| 7. Binds a ligand for IgA receptor         | major loop of HIV-2 (neutralizing)         |
| 8. An antibody that binds to a receptor    | HIV-1 MN                                   |
| 9. A growth factor                         | HIV-1 Thai-E                               |
| 10. PE domain                              | Binding motif for an MHC Class II molecule |
| 11.  | Binding motif for an MHC Class I molecule  |

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12. A non-native epitope domain of 5-1500 aa.

13. Different epitopes

14. Different epitopes from same pathogen

\_ or \_

12 ntPE-V3MN26 (which comprises all components);

13 ntPE-V3MN14 (which comprises all components)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:

Group I: Cell recognition domains are recited in claims 3-5.

Non-native epitopes are recited in claims 1,9,11,14,15-18.

The following claim(s) are generic: Claims 1, 24, 27 and 33

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4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each cell recognition domain, differs in both structure, function and biological effect, specifically the type of immune response induced. Each cell recognition domain will interact with a different type of receptor and will induce a different type of immune response. Each non-native epitope also differs in structure, function and biological effect. The different specificities of immune responses stimulated is directly correlated with the different sizes (5 to 1500 amino acids) and structures (linear or V3 loop apex). Thus each different species defines an independent and distinct invention, that is not linked by a shared special technical feature defined in claim 1, as Pastan et al (5,328,984) describes this feature.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp  
August 2, 2001

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600